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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
Petitioner

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

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BRIEF AMICUS CURIAE OF THE GROCERY MANUFACTURERS OF AMERICA, INC. IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI AND TO SUGGEST SUMMARY REVERSAL

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF AMICUS CURIAE.	1
QUESTION PRESENTED	2
STATEMENT OF THE CASE	2
REASONS FOR GRANTING THE PETITION	8
I. The Food Supply Unavoidably Contains Hundreds of "Added Poisonous or Deleterious Substances" at Trace Levels That Do Not Represent a Reasonable Possibility of Harm to Human Health Under Actual Conditions of Use	8
II. The Decision of the Court of Appeals Would Impose a Burdensome and Unreasonable Regulatory Scheme Without Any Public Health Benefit	11
III. The Decision of the Court of Appeals Conflicts with Two Authoritative Supreme Court Decisions	13
A. The *Lexington Mill* Decision Establishes FDA's Court Enforcement Authority Under Section 402(a)(1)	13
B. The Decision in *Heckler v. Chaney* Establishes That An FDA Administrative Determination Not to Initiate Court Enforcement Action Is Ordinarily Unreviewable in the Courts	14
IV. The Decision of the Court of Appeals Would Automatically Render the Vast Bulk of the American Food Supply Unlawful for the Foreseeable Future.	16
V. The Court Should Summarily Reverse the Decision of the Court of Appeals on the Basis of *Lexington Mill* and *Heckler v. Chaney*	18
CONCLUSION	19
APPENDIX A: ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED (FDA, SEPTEMBER 1982)	

TABLE OF AUTHORITIES

CASES:	Page
CIBA Corp. v. Weinberger, 412 U.S. 640 (1973)	14
Community Nutrition Institute v. Young, 757 F.2d 354 (D.C. Cir. 1985)	7
Flemming v. Florida Citrus Exchange, 358 U.S. 153 (1958)	5
Heckler v. Chaney, 105 S. Ct. 1649 (1985)	14-18
Industrial Union Dept, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980)	4
United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784 (1969)	17
United States v. Dotterweich, 320 U.S. 277 (1943)	17
United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914)	3, 4, 6, 7, 13, 18
United States v. 2,116 Boxes of Boned Beef, [1980-1981] Food Drug Cosm. L. Rep. (CCH) ¶ 38,114 (D. Kan. 1981)	5
Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973)	14
Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973)	12, 14

STATUTES AND REGULATIONS:	
34 Stat. 768 (1906)	2, 3
52 Stat. 1040 (1938)	2, 4
72 Stat. 1784 (1958)	9
5 U.S.C. § 556	12
5 U.S.C. § 557	12
21 U.S.C. § 301 et seq.	2, 4, 13, 14
21 U.S.C. § 342(a)(1)	4, 6, 7, 13, 14
21 U.S.C. § 342(a)(2)(A)	6
21 U.S.C. § 346	2, 6, 7, 10, 14, 16
21 C.F.R. § 10.30	13
21 C.F.R. § 109.5	13
21 C.F.R. § 109.30	11
44 Fed. Reg. 17070 (March 20, 1979)	9

Table of Authorities Continued

	Page
LEGISLATIVE MATERIALS:	
H.R. Rep. No. 2139, 75th Cong., 3d Sess. (1938)	6
S. Rep. No. 361, 74th Cong., 1st Sess. (1935)	5, 6
S. Rep. No. 493, 73d Cong., 2d Sess. (1934)	5, 6
"Foods, Drugs, and Cosmetics," Hearings before the Committee on Commerce, United States Senate, 73d Cong., 2d Sess. (1934)	4, 5
OTHER AUTHORITIES:	
Browne, Adulteration and the Condition of Analytical Chemistry Among the Ancients, 29 Science 455 (March 19, 1909)	9
Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 Tex. L. Rev. 1132 (1972)	12
Richardson et al., Sub-Part-Per-Trillion Detection of Riboflavin by Laser-Induced Fluorescence, 86 Analytica Chimica Acta 263 (1976)	9
Uniform Commercial Code § 2-314	18
Uniform Commercial Code § 2-315	18

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BRIEF AMICUS CURIAE OF THE GROCERY MANUFACTURERS OF AMERICA, INC. IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI AND TO SUGGEST SUMMARY REVERSAL

INTEREST OF AMICUS CURIAE

The Grocery Manufacturers of America, Inc. (GMA), is a trade association representing companies that manufacture food products for nationwide distribution. Its members include the principal grocery manufacturers in this country. Members of GMA ship products in interstate commerce for

sale throughout the country and thus are subject to all of the requirements established under the Federal Food, Drug, and Cosmetic Act of 1938 (the FD&C Act)[1] relating to food safety. GMA and its members therefore have a major interest in assuring that regulatory requirements relating to food safety conform to the provisions of the FD&C Act and impose no more burdensome procedural or substantive requirements than are reasonably necessary to maintain compliance with the Act. GMA and its members strongly support the current Food and Drug Administration (FDA) approach to regulating "added poisonous or deleterious substances" in the food supply under the FD&C Act, but oppose changes that would be required by the decision of the United States Court of Appeals for the District of Columbia Circuit in this case.[2]

QUESTION PRESENTED

Does the Federal Food, Drug, and Cosmetic Act of 1938 authorize the Food and Drug Administration to determine, through exercise of its administrative discretion, whether to regulate added poisonous or deleterious substances in the food supply by (1) establishing informal "action levels" that constitute criteria for determining when the FDA will initiate court enforcement proceedings under Section 402(a)(1) of the Act, without (2) establishing formal "tolerances" through rulemaking on a record under Section 406 of the Act that constitute substantive requirements under the Act?

STATEMENT OF THE CASE

In 1906, when the first national food safety legislation was enacted,[3] Congress declared that a food was adulterated, and thus illegal, if it contained:

[1]52 Stat. 1040 (1938), 21 U.S.C. § 301 et seq.

[2]All parties have consented to the filing of this brief by letters that have been filed with the clerk of the court in accordance with Rule 36.

[3]Food and Drugs Act of 1906, 34 Stat. 768 (1906).

> ". . . any added poisonous or other added deleterious ingredient which may render such article injurious to health . . ."[4]

In construing this statutory prohibition in the *Lexington Mill* case in 1914,[5] the Supreme Court rejected both the argument made by industry on the one extreme that food could be condemned only if it was shown actually to injure health, and the argument made by the government on the other extreme that food must be condemned if it contained even a harmless amount of a substance that would be poisonous or deleterious at a higher level:

> "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of establishing, in order to secure a verdict of condemnation under this statute, that the added poisonous or deleterious substances must be such as may render such article injurious to health. The word 'may' is here used in its ordinary and usual signification, there being nothing to show the intention of Congress to affix to it any other meaning. It is, says Webster, 'an auxiliary verb qualifying the meaning of another verb, by expressing ability,. . . contingency or liability, or possibility or probability.' In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the old and the young, the well and the sick; and it is

[4]Section 7, 34 Stat. at 770.

[5]United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914).

> intended that if any flour, because of any added poisonous or other deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act."[6]

Thus, this Court took the very reasonable intermediate position that an added poisonous or deleterious substance violated the law if it represented a reasonable possibility of harm to human health under its actual conditions of use.

When Congress enacted the Federal Food, Drug, and Cosmetic Act of 1938 (the FD&C Act)[7] to replace the 1906 Act, it retained, in Section 402(a)(1), the prohibition against any "added substance" in food that is a "poisonous or deleterious substance which may render it injurious to health."[8] The legislative history makes it clear that, although this provision was slightly reworded to fit the context of the new statute, Congress intended to retain the substance of the 1906 Act provision and this Court's 1914 interpretation of the provision. The Chief of the FDA, W.G. Campbell, testified before Congress in 1934 that the language of the provision in the pending legislation that became the 1938 Act:

> ". . . is the language of the present law. That language has been considered in litigation which was carried to

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[6]*Id.* at 411. This Court has, more recently, adopted virtually an identical interpretation of the Occupational Safety and Health Act. Industrial Union Dep't, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980).

[7]52 Stat. 1040 (1938), 21 U.S.C. § 301 et seq.

[8]Section 402(a)(1) of the FD&C Act, 21 U.S.C. § 342(a)(1).

> the Supreme Court, and has been very exhaustively discussed by that Court.
>
> Now, one of the concerns that we have is, first, the most extensive and most effective protections to the public that can be made. Unquestionably the use of the subjunctive provides that. And, second, to preserve the use of language which has already been considered by the Supreme Court."[9]

The committee reports in the Senate, which exercised the lead role in this legislation, reflected this intent of the draftsmen.[10] In fact, this Court has since recognized that its 1914 decision remains the controlling construction of the 1938 Act as well:

> "The language involved in *Lexington Mill* survived generally in the Act's broadest and most general test of food adulteration, § 402(a)(1)."[11]

Thus, Congress intended that the authority of FDA to enforce the statutory prohibition against added poisonous or deleterious substances would remain the same under the 1938 Act as under the 1906 Act.

Between 1906 and 1938, however, Congress realized that not all added poisonous or deleterious substances that may render food injurious to health can or should be prohibited. Some are vitally needed to produce an adequate supply of food at reasonable cost. Accordingly, the 1938 Act included,

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[9]"Foods, Drugs, and Cosmetics," Hearings before the Committee on Commerce, United States Senate, 73d Cong., 2d Sess. 530 (1934).

[10]S. Rep. No. 493, 73d Cong., 2d Sess. 3 (1934); S. Rep. No. 361, 74th Cong., 1st Sess. 6 (1935).

[11]Flemming v. Florida Citrus Exchange, 358 U.S. 153, 161 (1958). See, e.g., United States v. 2,116 Boxes of Boned Beef, [1980-1981] Food Drug Cosm. L. Rep. (CCH) ¶ 38,114 (D. Kan. 1981).

for the first time, a provision, Section 406,[12] authorizing FDA to set tolerances for added poisonous or deleterious substances that would otherwise be banned under Section 402(a)(1) where those substances are required in the production of food or cannot be avoided by good manufacturing practice.[13] Under these circumstances, FDA was specifically given the authority to set formal tolerances, after rulemaking on a record, to establish whatever limitations are necessary for the protection of the public health. The legislative history reveals that this provision was designed to permit residues of pesticides, other added substances, and environmental contaminants.[14] This authority was intended to be in addition to, and in no way to detract from, the pre-existing prohibition against added poisonous or deleterious substances that was retained in Section 402(a)(1).

Since 1938, FDA has followed the clear intent of Congress by bringing enforcement action against added poisonous or deleterious substances under Section 402(a)(1) and, in one instance, by establishing a formal tolerance under Section 406 of the Act. To bridge these two closely-related statutory provisions, FDA has issued informal "action levels" for added poisonous or deleterious ingredients in food that serve two purposes. First, they inform the public of those levels of added poisonous or deleterious substances that do not represent a reasonable possibility of harm under actual conditions of use and thus against which enforcement is not warranted under the 1914 Supreme Court's *Lexington Mill*

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[12]21 U.S.C. § 346.

[13]For such a substance, Section 402(a)(2)(A), 21 U.S.C § 342(a)(2)(A), provides that the failure to comply with a promulgated tolerance renders the food adulterated and thus unlawful.

[14]See, e.g., S. Rep. No. 493, 73d Cong., 2d Sess. 4 (1934); S. Rep. No. 361, 74th Cong., 1st Sess. 6 (1935); and H.R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (1938).

interpretation of the safety standard in Section 402(a)(1). Second, they inform the public of the levels of added poisonous or deleterious substances that would be set at that moment under the authority of Section 406 if FDA concluded that it was a wise expenditure of scarce administrative resources to undertake a formal rulemaking proceeding to establish such tolerances. In both respects, the result is the same—FDA establishes a level of exposure that is sufficient to assure that the food does not present a reasonable possibility of harm to human health under actual conditions of use, and thus that provides a sufficient margin of safety to protect the public health.

This system has functioned smoothly for almost 50 years. The action levels currently established by FDA under this system, as contained in the official FDA publication, are reproduced in Appendix A to this brief. There is no evidence that these action levels fail adequately to protect the public health.

In 1982, however, the Community Nutrition Institute (CNI), et al., filed suit to contest the legality of this long-established interpretation and application of the law. CNI sought to require FDA to establish a formal tolerance under Section 406, through rulemaking on a record, for every added poisonous or deleterious substance in the food supply. After the district court rejected CNI's position, the court of appeals upheld it.[15] The Solicitor General has petitioned for a writ of certiorari. This brief amicus curiae is submitted in support of the petition, and to suggest that the Court summarily reverse the decision of the court of appeals on the basis that it conflicts with two controlling Supreme Court precedents.

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[15]Community Nutrition Institute v. Young, 757 F.2d 354 (D.C. Cir. 1985).

REASONS FOR GRANTING THE PETITION

The decision of the court of appeals—which would overturn FDA's long-established administrative interpretation of the law, impose in its place an unreasonable and burdensome new regulatory scheme that will not increase public health protection, conflict with two authoritative Supreme Court decisions, and render the vast bulk of the American food supply unlawful for the foreseeable future—is clearly incorrect. This Court should therefore grant the petition for a writ of certiorari and summarily reverse the court of appeals.

I. The Food Supply Unavoidably Contains Hundreds of "Added Poisonous or Deleterious Substances" at Trace Levels That Do Not Represent a Reasonable Possibility of Harm to Human Health Under Actual Conditions of Use.

Throughout history, the food supply has always contained trace amounts of substances that are unavoidably added in the course of food production and processing. As part of the industrial revolution, our large urban centers developed, and people no longer grew their own food. Dramatic changes were needed in food production, transportation, processing, packaging, and preservation in order to accommodate this new national lifestyle. Society increasingly depended upon chemicals of both natural and synthetic origin to serve these purposes, and the number and frequency of trace amounts of these substances in the food supply therefore inevitably increased.

Although these unavoidable added substances have always been present, they have not always been detectable by the scientific methodology available to analytical chemists. At the beginning of this century, for example, when the 1906 Act was enacted, analytical methodology was basically qualitative rather than quantitative in nature and in some

respects had advanced very little beyond what was known and practiced in ancient Greece and Rome.[16] By the time that the 1938 Act was passed, analytical methodology had become more quantitative in nature, but was accurate only at relatively high levels. When the Food Additives Amendment of 1958[17] was enacted, the sensitivity of detection methodology had been reduced to the relatively high parts per million (ppm) level. During the past 30 years, it has progressively been reduced first to the very low ppm level, then to parts per billion (ppb) and parts per trillion (ppt), and now to parts per quadrillion (ppq).[18] In a preamble to a proposed regulation published by FDA in 1979, the agency described this:

> ". . . trend of the increasing capacity of analytical chemistry to detect [and] measure the presence of chemicals. Depending on the substance or class of substances, this decrease in the lowest limits of measurement during the last 20 years ranges between two and five orders of magnitude [i.e., between 100 and 100,000 times]."[19]

It is helpful, in appreciating the significance of these levels, to realize that one ppb, which is now commonplace for all

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[16]Browne, Adulteration and the Condition of Analytical Chemistry Among the Ancients, 29 Science 455 (March 19, 1909). Dr. Browne served as President of the Association of Official Analytical Chemists in 1925 and as Commissioner of Food and Drugs during 1923-1927.

[17]72 Stat. 1784 (1958).

[18]E.g., Richardson et al., Sub-Part-Per-Trillion Detection of Riboflavin by Laser-Induced Fluorescence, 86 Analytica Chimica Acta 263 (1976).

[19]44 Fed. Reg. 17070, 17075 (March 20, 1979). The notice included tables showing the increased sensitivity of the analytical detection methodology for specific chemicals. Id. at 17076-17077.

detection methodology, is equivalent to one second in 32 years or one inch in 16,000 miles.

With every incremental advance in the science of analytical chemistry, more and more added substances have been found at trace levels in the American food supply. Most, if not all, of these added substances would be regarded as "poisonous or deleterious" at higher levels of use, but pose no reasonable possibility of harm to human health under their actual conditions of use. Poisonous or deleterious substances that could not be found at the ppm level can often be found at the ppb or ppt level, and are even more certain to be found at the ppq level. Although it appeared in 1938, when Section 406 was enacted, that there were relatively few unavoidable poisonous or deleterious substances to be found in food, it is now apparent that there are literally hundreds of them.

Were it not for the statutory interpretation of the food safety provisions of the FD&C Act adopted and consistently applied by FDA, this would have become a regulatory nightmare both for FDA and for the food industry. As more and more poisonous or deleterious substances are found at low levels, decisions must be made by FDA on how best to handle them in order to assure a safe food supply for the American public.

Under the FDA regulatory approach that has prevailed for the past half century, this has proved to be a manageable task. For those trace poisonous or deleterious substances that represent a trivial risk, FDA simply ignores their presence and does not establish either an informal action level or a formal tolerance. For those that are found at levels that could potentially approach amounts of public health concern, action levels (shown in Appendix A) have been established to make certain that they represent no reasonable possibility of harm to human health. As more has become known about those substances (and their toxicity and level of human exposure), those action levels have been changed over time. In the one instance where sufficient data have accumulated to permit a permanent maximum level, and persistent litigation justified the time and expense involved in the administrative proceeding, a formal tolerance has been promulgated on the basis of a rulemaking on a record.[20]

This approach is sensible and has in fact worked very well to protect the health of the American public. FDA has established conservative levels for added poisonous or deleterious substances and in fact no human toxicity has been traced to them.

II. The Decision of the Court of Appeals Would Impose a Burdensome and Unreasonable Regulatory Scheme Without Any Public Health Benefit.

In place of the existing common sense approach that has prevailed for the past 50 years, the court of appeals would arbitrarily require an expensive and time-consuming new scheme that would serve no public health purpose. The novel interpretation advanced by the court of appeals would require the formal establishment of a tolerance under Section 406, based upon rulemaking on a record, for every poisonous or deleterious substance found in the food supply. At the outset, this would encompass all of the substances, and all of the uses specified, in the current FDA action levels reprinted in Appendix A.

This would, however, only be the beginning. Many of the poisonous or deleterious substances listed in Appendix A can readily be found, under modern methods of analytical

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[20] 21 C.F.R. § 109.30 (polychlorinated biphenyls).

chemistry, in other foods as well. And as analytical methods become increasingly more sensitive, they will be found in still other food products.

Nor would this be the end of the matter. There are hundreds of poisonous or deleterious substances presently found in the food supply, under extremely sensitive detection methodology, which present such a trivial risk that FDA has not bothered to list them or to establish an action level. Under the extreme interpretation of the court of appeals, however, FDA would be required to establish a formal tolerance even for these substances, to avoid the food becoming unlawful per se.

All of this would be required solely in the name of strict statutory construction, with no attention paid to the overall statutory structure or to the protection of the public health. Scarce agency and industry resources would be channeled away from productive enterprise into formal rulemaking proceedings designed solely to satisfy procedural requirements. Formal rulemaking on a record, which is subject to the strict requirements for adjudication under the Administrative Procedure Act,[21] is resource-intensive and imposes substantial burdens upon FDA and the regulated industry.[22] There has been, and can be, no suggestion that any of these proceedings would advance public health objectives.

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[21]5 U.S.C. § 556 and § 557.

[22]See, e.g. Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 Tex. L. Rev. 1132 (1972). The enormous administrative burden that would have been imposed by the requirement of hundreds of such formal administrative hearings was one factor that led this Court to conclude that the FD&C Act should not be interpreted to incorporate such a requirement for all new drug application withdrawals in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 621 (1973).

To the extent that any person believes that a current FDA action level is too high (or too low), or that a poisonous or deleterious substance found at trace levels that represent only a trivial risk should be regulated through an action level, procedural remedies are presently available. FDA has promulgated regulations establishing the right of any person to petition FDA for appropriate action under these circumstances.[23] There is no need to establish an entire new regulatory scheme in order to assure adequate protection both of the procedural rights of interested persons and of the substantive right to a safe food supply.

III. The Decision of the Court of Appeals Conflicts With Two Authoritative Supreme Court Decisions.

The decision of the court of appeals in this case is fundamentally in conflict with two major Supreme Court decisions, one of which was decided less than a week before the decision in this case.

A. The *Lexington Mill* Decision Establishes FDA's Court Enforcement Authority Under Section 402(a)(1).

As noted above, the prohibition against added poisonous or deleterious substances under the 1906 Act, as interpreted by this Court in the *Lexington Mill* case in 1914, was explicitly retained by Congress under the 1938 Act.[24] Thus, Congress intended FDA to continue to exercise its administrative enforcement discretion to determine whether it was reasonably possible that an added poisonous or deleterious substance would render food injurious to health under actual conditions of use. There is no legislative history to support the view, advanced by the court of appeals, that

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[23]21 C.F.R. § 109.5 and § 10.30.

[24]Notes 9-11 *supra* and accompanying text.

enactment of Section 406 qualified or overruled this independent court enforcement authority.

This Court has, in an analogous context, recognized that FDA has been given two independent methods of enforcing a common statutory objective—administrative rulemaking proceedings and direct action in the courts. In the Bentex[25] andCIBA[26] cases, the Court held that FDA has primary jurisdiction to decide with administrative finality the regulatory status of products within its jurisdiction and, at the same time, independently has administrative discretion to initiate enforcement action directly in the courts. The CIBA decision explicitly recognized the power of FDA to initiate court enforcement action without first undertaking an administrative proceeding. The same logic applies here as well. Thus, the provisions of Section 406, relating to administrative proceedings, should in no way interfere with the provisions of Section 402(a)(1) authorizing court enforcement proceedings.

B. The Decision in Heckler v. Chaney Establishes That An FDA Administrative Determination Not To Initiate Court Enforcement Action Is Ordinarily Unreviewable In The Courts.

Just six days after the court of appeals handed down its decision in the instant case, the Supreme Court handed down its decision in *Heckler v. Chaney*.[27] It is apparent that the decision of the court of appeals is in serious conflict with the *Chaney* decision.

In *Chaney*, the Court held that an FDA decision not to initiate court enforcement action is ordinarily unreviewable

[25]Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973).

[26]CIBA Corp. v. Weinberger, 412 U.S. 640, 643-644 (1973).

[27]Heckler v. Chaney, 105 S. Ct. 1649 (1985).

in the courts. Absent fraud or other extraordinary circumstances, enforcement decisions are "committed to agency discretion" under the Administrative Procedure Act. The Court explained some of the "administrative concerns" which underlie this policy:

> "First, an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities. Similar concerns animate the principles of administrative law that courts generally will defer to an agency's construction of the statute it is charged with implementing, and to the procedures it adopts for implementing that statute."[28]

These "administrative concerns" describe, of course, the very reasons why FDA enforcement of the food safety provisions of the law must remain within the scope of administrative discretion.

The decision of the court of appeals, however, takes the matter entirely out of FDA's administrative discretion and requires the agency to establish formal tolerances, through

[28]Id. at 1656.

rulemaking on a record, for each and every poisonous or deleterious substance found in the food supply. Under the interpretation adopted by the court of appeals, FDA's deployment of resources, and ordering of priorities, would be dictated by procedures imposed by the judiciary and not by public health concerns. They would be required for purely procedural rather than substantive reasons. The approach adopted by the court of appeals is thus irreconcilable with the approach of this Court in *Chaney*.

Even if formal tolerances were adopted for all poisonous or deleterious substances under Section 406, the *Chaney* decision—handed down just a few days before the decision in the instant case, and clearly not considered by the court of appeals in arriving at its own decision—would make them a procedural nicety and a substantive nullity. Enforcement priorities would remain discretionary with FDA regardless of the procedure imposed upon FDA in establishing unacceptable levels of poisonous or deleterious substances in the food supply. It makes little sense to reorder FDA's priorities, and to abrogate a well-established food safety regulatory program that has stood the test of 50 years of experience, when the end result will be no different than it is now.

IV. The Decision of the Court of Appeals Would Automatically Render the Vast Bulk of the American Food Supply Unlawful for the Foreseeable Future.

The action levels that would be invalidated by the court of appeals, as shown in Appendix A, pertain to a substantial portion of this country's food supply. Under the novel interpretation adopted by the court of appeals, all of the food covered by those action levels would instantly become adulterated and thus illegal per se under the FD&C Act. Equally important, all other foods which contain added poisonous or deleterious substances that FDA has determined to present only a trivial risk, and thus do not justify even an action level, would be equally unlawful. With the extraordinary sensitivity of detection methodology now available to analytical chemists, it is difficult to imagine many foods, if any, that would escape this broad condemnation.

Even with heroic efforts and the deployment of a substantial portion of FDA personnel, it is unlikely that administrative proceedings could be initiated and completed for all of these added poisonous or deleterious substances in all of the myriad foods that comprise our national diet.[29] It is likely that, as soon as one proceeding was completed, other added poisonous or deleterious substances would be detected in still other foods. It is thus questionable whether FDA could ever catch up with the problem, or would forever be chasing an unachievable administrative goal.

This regulatory dilemma only serves to underscore the impractical and unrealistic interpretation adopted by the court of appeals, and the sound policy reasons for the consistent administrative interpretation adopted by FDA of these provisions for the past 50 years. As this Court has recognized, the FD&C Act "is to be treated as a working instrument of government and not merely as a collection of English words"[30] and thus must be given "a liberal construction consistent with the Act's overriding purpose to protect the public health."[31] Formalistic requirement of rigid Section 406 tolerances, after rulemaking on a record, will achieve no such purpose.

It is no comfort to the food industry that, under the *Chaney* decision, FDA undoubtedly would exercise its in-

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[29]Note 22 *supra*.

[30]United States v. Dotterweich, 320 U.S. 277, 280 (1943).

[31]United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969).

herent administrative discretion not to initiate court enforcement action against the entire food supply or even those foods for which action levels have been established as shown in Appendix A. There are serious commercial implications that could flow from the decision of the court of appeals as well. Under the Uniform Commercial Code, all food is sold subject to the implied warranties of merchantability and fitness for the intended purpose.[32] Food that is in violation of federal law could readily be regarded as in violation of this implied warranty. Accordingly, the decision by the court of appeals could jeopardize virtually all commercial transactions in the food industry. Those who sought a way to abrogate contracts for the sale of food need look no further than the decision of the court of appeals in the instant case.

V. This Court Should Summarily Reverse the Decision of the Court of Appeals on the Basis of Lexington Mill and Heckler v. Chaney.

As demonstrated in Part III of this brief, the decision of the court of appeals contradicts the decisions of this Court in *Lexington Mill* and *Heckler v. Chaney*. The decision in *Heckler v. Chaney*, moreover, preceded the decision in the instant case by only six days and thus clearly was not considered by the court of appeals. Accordingly, this Court should summarily reverse the court of appeals, without the need for further briefing or oral argument, on the basis of those two controlling precedents.

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[32]Uniform Commercial Code § 2-314 and § 2-315.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted and the decision of the court of appeals should summarily be reversed.

Respectfully submitted,

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APPENDIX A

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

Action levels for poisonous or deleterious substances are established by the Food and Drug Administration (FDA) to control levels of contaminants in human food and animal feed.

The action levels are established and revised according to criteria specified in Title 21, *Code of Federal Regulations*, Parts 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective.

Action levels and tolerances represent limits at or above which FDA will take legal action to remove adulterated products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant.

Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable. The blending of a food or feed containing a substance in excess of an action level or tolerance with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

This booklet lists action levels established by the FDA for poisonous or deleterious substances in human food and animal feed. This list is current as of September, 1982. Notices will be published in the *Federal Register* as new action levels are established or as existing action levels are revised or revoked. It is the responsibility of the user of the list to keep up to date on changes in the action levels.

Single *copies* of this booklet are available from:

Food and Drug Administration
Industry Programs Branch
Bureau of Foods (HFF-326)
200 C Street, S.W.
Washington, D.C. 20204
Phone (202) 245-1523

Copies of the *Compliance Policy Guides* (CPG) referenced in the action level list may be obtained from:

Food and Drug Administration
Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857
Phone (301) 443-6310

Other *references* in the action level list are filed under Docket No. 77N-0166 for public viewing at:

Food and Drug Administration
Docket's Management Branch (HFA-305)
5600 Fishers Lane
Rockville, Maryland 20857
Phone (301) 443-1753

For further *assistance or information* contact:

Food and Drug Administration
Guidelines and Compliance Research Branch
Bureau of Foods (HFF-312)
200 C Street, S.W.
Washington, D.C. 20204
Phone (202) 245-3092

FDA ACTION LEVELS
INDEX

SUBSTANCE	PAGE
Aflatoxin	1
Aldrin & Dieldrin	1
Benzene Hexachloride (BHC)	2
Cadmium	3
Chlordane	3
Crotalaria Seeds	3
Dibromochloropropane (DBCP)	4
DDT, DDE, TDE	4
Endrin	5
Fenthion	6
Heptachlor & Heptachlor Epoxide	7
Kelthane	8
Kepone	8
Lead	9
Lindane	10
Mercury	11
Methyl Alcohol	11
Mirex	11
Nitrosodimethylamine (NDMA)	11
Paralytic Shellfish Toxin	12
Polybrominated Biphenyls (PBB's)	12
Polychlorinated Biphenyls (PCB's)	13
Toxaphene	13

FDA ACTION LEVELS

AFLATOXIN

Commodity	Action Level	Reference
Brazil nuts	20.0 mcgs/kg	CPG 7112.07
Feeds and feed ingredients	20.0 ppb	CPG 7126.33
Foods	20.0 mcgs/kg	CPG 7120.26
Milk	0.5 ppb (aflatoxin M_1)	CPG 7106.10
Peanuts & peanut products	20.0 mcgs/kg	CPG 7112.02
Pistachio nuts	20.0 mcgs/kg	CPG 7112.08

ALDRIN & DIELDRIN

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at a level below 0.03 ppm for nonfatty foods and 0.3 ppm for fish and for milk.

Commodity	Action Level	Reference
Animal feed, finished, processed	0.03 ppm	CPG 7126.27-A
Artichokes	0.05 ppm	CPG 7120.23-A
Eggs	0.03 ppm	CPG 7120.23-A
Fats & oils: animal, vegetable fish (animal feed)	0.3 ppm	CPG 7126.27-A
Fish and shellfish	0.3 ppm	CPG 7120.23-A
Figs	0.05 ppm	CPG 7120.23-A
Hay (animal feed)	0.03 ppm	CPG 7126.27-A

Melons[1]	0.15 ppm	CPG 7120.23-A
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-A
Small fruits[1,2]	0.05 ppm	CPG 7120.23-A
Sugarbeet pulp (animal feed)	0.1 ppm	CPG 7126.27-A

[1]Other than those commodities specified in 40 C.F.R 180.135 and 180.137.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

BENZENE HEXACHLORIDE (BHC)

The figures below are for residues of total BHC. However, in adding amounts of individual isomers do not count alpha, gamma or delta BHC at a level below 0.1 ppm in milk or eggs and below 0.02 in other products. Do not count beta BHC at a level below 0.2 in milk or eggs and below 0.04 in other products.

Commodity	Action Level	Reference
Animal feed, processed	0.1 ppm	CPG 7126.27-B
Barley, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Barley, grain (human food)	0.1 ppm	CPG 7120.23-B
Beans	0.5 ppm	CPG 7120.23-B
Citrus fruit[2]	0.5 ppm	CPG 7120.23-B
Cocoa beans, whole raw bean	0.5 ppm	CPG 7120.23-B
Corn, fresh sweet	0.5 ppm	CPG 7120.23-B
Corn, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Corn, grain (human food)	0.1 ppm	CPG 7120.23-B
Eggs	0.5 ppm	CPG 7120.23-B
Endive	0.5 ppm	CPG 7120.23-B
Figs	0.5 ppm	CPG 7120.23-B
Frog legs	0.5 ppm	CPG 7120.23-B
Guavas	0.5 ppm	CPG 7120.23-B
Hays (animal feed)	0.1 ppm	CPG 7126.27-B
Mangoes	0.5 ppm	CPG 7120.23-B
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-B
Milo, sorghums (animal feed)	0.1 ppm	CPG 7126.27-B
Milo, sorghums (human food)	0.1 ppm	CPG 7120.23-B
Oats, grain (animal feed)	0.1 ppm	CPG 7126.27-B

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Oats, grain (human food)	0.1 ppm	CPG 7120.23-B
Peas	0.5 ppm	CPG 7120.23-B
Pineapples	0.5 ppm	CPG 7120.23-B
Quinces	0.5 ppm	CPG 7120.23-B
Root vegetables[2]	0.5 ppm	CPG 7120.23-B
Rice, grain	0.1 ppm	CPG 7120.23-B
Rye, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Rye, grain (human food)	0.1 ppm	CPG 7120.23-B
Small fruits[1],[2]	0.5 ppm	CPG 7120.23-B
Turnip greens	0.5 ppm	CPG 7120.23-B
Wheat, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Wheat, grain (human food)	0.1 ppm	CPG 7120.23-B

[1]Other than those commodities specified in 40 C.F.R. 180.146.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

CADMIUM

Commodity	Action Level	Reference
Pottery(ceramics)		CPG 7117.06
Flatware (ave. of 6 units)	0.5 mcgs/ml of leaching solution	
Small hollowware (any one of 6 units)	0.5 mcgs/ml of leaching solution	CPG 7117.06
Large hollowware (any one of 6 units)	0.25 mcgs/ml of leaching solution	CPG 7117.06

CHLORDANE

Commodity	Action Level	Reference
Animal fat, rendered	0.8 ppm	CPG 7126.27-C
Animal feed	0.1 ppm	CPG 7126.27-C
Fish	0.3 ppm	CPG 7120.23-C

CROTALARIA SEEDS
(C. spectabilis and/or C. sagittalis and/or C. striata)

Commodity	Action Level	Reference
Grains and Feeds	Average of 1 whole seed/pound	CPG 7126.15

FDA ACTION LEVELS

DIBROMOCHLOROPROPANE (DBCP)

Commodity	Action Level	Reference
Milk	1.5 ppm (fat basis)	CPG 7120.23-E
Raw agricultural commodities (except milk)	0.05 ppm	CPG 7120.23-E

DDT, DDE, AND TDE

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of DDT, DDE and TDE do not count any of the three found below 0.2 ppm for fish, eggs, and grain.

Commodity	Action Level	Reference
Animal feed, processed	0.5 ppm	CPG 7126.27-D
Barley, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Barley, grain (human food)	0.5 ppm	CPG 7120.23-D
Cocoa beans, whole raw bean	2.0 ppm	CPG 7120.23-D
Corn, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Corn, grain (human food)	0.5 ppm	CPG 7120.23-D
Eggs	1.5 ppm	CPG 7120.23-D
Fish	5.0 ppm	CPG 7120.23-D
Hay	0.5 ppm	CPG 7126.27-D
Milo (sorghum), grain (animal feed)	0.5 ppm	CPG 7126.27-D
Milo (sorghum), grain (human food)	0.5 ppm	CPG 7120.23-D
Oats, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Oats, grain (human food)	0.5 ppm	CPG 7120.23-D
Rice, grain (animal feed)	0.5 ppm	CPG 7126.27-D

Rice, grain (human food)	0.5 ppm	CPG 7120.23-D
Rye, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Rye, grain (human food)	0.5 ppm	CPG 7120.23-D
Wheat, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Wheat, grain (human food)	0.5 ppm	CPG 7120.23-D

FDA ACTION LEVELS

ENDRIN

Commodity	Action Level	Reference
Animal feed, processed	0.03 ppm	CPG 7126.27-E
Asparagus	0.05 ppm	CPG 7120.23-F
Beans	0.05 ppm	CPG 7120.23-F
Citrus fruits[2]	0.05 ppm	CPG 7120.23-F
Corn, fresh sweet	0.05 ppm	CPG 7120.23-F
Eggs	0.03 ppm	CPG 7120.23-F
Figs	0.05 ppm	CPG 7120.23-F
Fish and shellfish	0.3 ppm	CPG 7120.23-F
Fish meal, fish solubles, fish oil (animal feed)	0.3 ppm	CPG 7126.27-E
Guavas	0.05 ppm	CPG 7120.23-F
Leafy vegetables[1],[2]	0.05 ppm	CPG 7120.23-F
Mangoes	0.05 ppm	CPG 7120.23-F
Melons	0.05 ppm	CPG 7120.23-F
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-F
Oilseed meal-peanut, soybean, cottonseed, etc. (animal feed)	0.03 ppm	CPG 7126.27-E
Okra	0.05 ppm	CPG 7120.23-F
Peas	0.05 ppm	CPG 7120.23-F
Pimentoes	0.05 ppm	CPG 7120.23-F
Pineapples	0.05 ppm	CPG 7120.23-F
Pome fruits[2]	0.05 ppm	CPG 7120.23-F
Pumpkins	0.05 ppm	CPG 7120.23-F
Root vegetables[1],[2]	0.05 ppm	CPG 7120.23-F
Small fruits[2]	0.05 ppm	CPG 7120.23-F
Stone fruits[2]	0.05 ppm	CPG 7120.23-F

[1]Other than those commodities specified in 40 C.F.R. 180.131.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Vegetable oils and fats, including soapstock (animal feed)	0.3 ppm	CPG 7126.27-E

FDA ACTION LEVELS

FENTHION

Commodity	Action Level	Reference
Ground red peppers	0.3 ppm	CPG 7120.23-G

FDA ACTION LEVELS

HEPTACHLOR AND HEPTACHLOR EPOXIDE

The figures below are for residues of the above pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found at a level below 0.3 ppm for fish and 0.03 ppm for other products.

Commodity	Action Level	Reference
Animal feed, processed	0.03 ppm	CPG 7126.27-F
Artichokes	0.05 ppm	CPG 7120.23-H
Asparagus	0.05 ppm	CPG 7120.23-H
Beans, except snap beans	0.05 ppm	CPG 7120.23-H
Citrus fruits[2]	0.05 ppm	CPG 7120.23-H
Cucumbers	0.05 ppm	CPG 7120.23-H
Dairy products (manufactured)[1]	0.1 ppm	CPG 7120.23-H
Eggs	0.03 ppm	CPG 7120.23-H
Eggplant	0.05 ppm	CPG 7120.23-H
Figs	0.05 ppm	CPG 7120.23-H
Fish and shellfish	0.3 ppm	CPG 7120.23-H
Leafy vegetables	0.05 ppm	CPG 7120.23-H
Hays[1]	0.03 ppm	CPG 7126.27-F
Melons	0.05 ppm	CPG 7120.23-H
Okra	0.05 ppm	CPG 7120.23-H
Pears	0.05 ppm	CPG 7120.23-H
Pimentoes	0.05 ppm	CPG 7120.23-H
Pumpkins	0.05 ppm	CPG 7120.23-H
Quinces	0.05 ppm	CPG 7120.23-H
Rice, grain, (animal feed)	0.03 ppm	CPG 7126.27-F
Rice, grain (human food)	0.03 ppm	CPG 7120.23-H
Small fruits[1],[2]	0.05 ppm	CPG 7120.23-H

[1]Other than those commodities specified in 40 C.F.R. 180.104 and 180.319.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Stone fruits[1],[2]	0.05 ppm	CPG 7120.23-H
Squash (summer or winter)	0.05 ppm	CPG 7120.23-H

[1]Other than those commodities specified in 40 C.F.R. 180.104 and 180.319.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

KELTHANE
[1,1 Bis (p-chlorophenyl)-2,2,2-trichloroethanol]

Commodity	Action Level	Reference
Animal feed, finished processed	0.5 ppm	CPG 7126.27-H

KEPONE
[Decachlorooctahydro-1,3,4-methano-2H-cyclobuta (cd) pentalen-2-one]

Commodity	Action Level	Reference
Crabmeat	0.4 ppm	CPG 7120.23-I
Fish	0.3 ppm	CPG 7120.23-I
Shellfish	0.3 ppm	CPG 7120.23-I

FDA ACTION LEVELS

LEAD

Commodity	Action Level	Reference
Pottery (ceramics)		CPG 7117.07
Flatware (ave. of 6 units)	7.0 mcgs/ml of leaching solution	
Small hollowware (any one of 6 units)	5.0 mcgs/ml of leaching solution	CPG 7117.07
Large hollowware (any one of 6 units)	2.5 mcgs/ml of leaching solution	CPG 7117.07
Silver-plated hollowware (ave. of 6 units)	7.0 mcgs/ml of leaching solution if product intended for use by adults	CPG 7117.05
Silver-plated hollowware (one or more of 6 units)	0.5 mcgs/ml of leaching solution if product intended for use by infants and children	CPG 7117.05

FDA ACTION LEVELS

LINDANE

Commodity	Action Level	Reference
Animal feed, processed	0.1 ppm	CPG 7126.27-H
Artichokes	0.5 ppm	CPG 7120.23-J
Barley, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Barley (human food)	0.1 ppm	CPG 7120.23-J
Beans	0.5 ppm	CPG 7120.23-J
Citrus fruit[2]	0.5 ppm	CPG 7120.23-J
Cocoa beans, whole raw bean	0.5 ppm	CPG 7120.23-J
Corn, fresh sweet	0.5 ppm	CPG 7120.23-J
Corn, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Corn, grain (human food)	0.1 ppm	CPG 7120.23-J
Eggs	0.5 ppm	CPG 7120.23-J
Endive	0.5 ppm	CPG 7120.23-J
Figs	0.5 ppm	CPG 7120.23-J
Hays	0.1 ppm	CPG 7126.27-H
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-J
Milo (sorghum), grain (animal feed)	0.1 ppm	CPG 7126.27-H
Milo (sorghum), grain, (human food)	0.1 ppm	CPG 7120.23-J
Oats, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Oats, grain (human food)	0.1 ppm	CPG 7120.23-J
Peas	0.5 ppm	CPG 7120.23-J
Rice, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Rice, grain (human food)	0.1 ppm	CPC 7120.23-J
Root vegetables[1],[2]	0.5 ppm	CPG 7120.23-J
Rye, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Rye, grain (human food)	0.1 ppm	CPG 7120.23-J

[1]Other than those commodities specified in 40 C.F.R. 180.133.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Small fruits[1],[2]	0.5 ppm	CPG 7120.23-J
Turnip greens	0.5 ppm	CPG 7120.23-J
Wheat, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Wheat, grain (human food)	0.1 ppm	CPG 7120.23-J

[1]Other than those commodities specified in 40 C.F.R. 180.133.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

MERCURY

Commodity	Action Level	Reference
Fish, shellfish, crustaceans, other aquatic animals. Edible portion only. Fresh, frozen or processed.	1.0 ppm	CPG 7108.07
Wheat (pink kernals only)	1.0 ppm	CPG 7104.05

METHYL ALCOHOL

Commodity	Action Level	Reference
Imported brandy	0.35%	CPG 7119.09

MIREX

Commodity	Action Level	Reference
Fish	0.1 ppm	CPG 7120.23-K

NITROSODIMETHYLAMINE (NDMA)

Commodity	Action Level	Reference
Barley Malt	10 ppb	CPG 7104.07
Malt Beverages	5 ppb	CPG 7101.07

FDA ACTION LEVELS

PARALYTIC SHELLFISH TOXIN

Commodity	Action Level	Reference
Clams (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20
Mussels (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20
Oysters (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20

POLYBROMINATED BIPHENYLS (PBB's)

Commodity	Action Level	Reference
Milk & dairy products (fat basis)	0.3 ppm	"A Review of Congressman William M. Brodhead's Petition to Reduce FDA Action Levels for Polybrominated Biphenyls (PBB) in Food", July 27, 1977
Meat (fat basis)	0.3 ppm	
Eggs	0.05 ppm	
Animal Feed	0.05 ppm	

FDA ACTION LEVELS

POLYCHLORINATED BIPHENYLS (PCB's)

Commodity	Action Level	Reference
Paper food-packaging material intended for or used with human food, finished animal feed and components intended for animal feeds	10 ppm	21 CFR 109.30 (a)(9) and 509.30 (a)(9) Tolerance stayed on 8-24-73 (38 FR 22794) 21 CFR 109.6(d) and 509.6(d)
Red Meat	3 ppm (fat basis)	CPG 7111.03

TOXAPHENE

Commodity	Action Level	Reference
Animal feed, processed	0.5 ppm	CPG 7126.27-I
Artichokes	1.0 ppm	CPG 7120.23-L
Asparagus	1.0 ppm	CPG 7120.23-L
Cherries	1.0 ppm	CPG 7120.23-L
Figs	1.0 ppm	CPG 7120.23-L
Fish	5.0 ppm	CPG 7120.23-L
Melons	1.0 ppm	CPG 7120.23-L
Mustard greens	1.0 ppm	CPG 7120.23-L
Plums	1.0 ppm	CPG 7120.23-L
Pumpkins	1.0 ppm	CPG 7120.23-L
Root vegetables[1],[2]	1.0 ppm	CPG 7120.23-L
Small fruits[1],[2]	1.0 ppm	CPG 7120.23-L

[1]Other than those commodities specified in 40 C.F.R. 180.138.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Squash (summer or winter)	1.0 ppm	CPG 7120.23-L
Turnip greens	1.0 ppm	CPG 7120.23-L